REMARKS

I. Status of Claims.

Claims 1-9, 12-23, 26-41 and 44 are pending.

Claims 1, 15 and 44 are amended in a manner that is believed to overcome rejections contained in the pending Office Action. Support for these amendments can be found throughout the drawings and specification. Claims 4 and 29 have been cancelled by the instant amendment as being drawn to duplicitous subject matter. No new matter or issues are introduced by these amendments.

II. Rejection of claims 1, 3, 9, 12, 15, 17 and 29-31 under 35 U.S.C. §102 (b).

The Examiner rejected claims 1, 3, 9, 12, 15, 17 and 29-31 under 35 U.S.C. §102 (b) as being anticipated by Fox et al. EP 038421 (Fox). Applicants have amended claims 1 and 15, from which all rejected claims depend, to further emphasize their invention.

A. Examiner's Rejection: The Examiner states that Fox discloses a method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers and antimicrobial agents. The Examiner further states that Fox also discloses a method of preparing an infection-resistant surface, characterized by preparing a coating vehicle by dispensing a matrix forming polymeric material selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers and antimicrobial agents.

B. Applicants' Claimed Invention: As amended, the claimed invention is more clearly directed to a coating composition including a combination of RTV silicone and urethane and a method of preparation. The combination of "RTV silicone and urethane, wherein said RTV silicone is selected from the group consisting of methyltri-methoxy silane, methyltri-acetoxy silane, tetrachlorosilane, vinyl trimethoryl silane, organosilane ester tris[3-(trimethoxysilyl)propyl] isocyanurate, bis[trimethoxysilyl)propyl] amine and gamma-

ureidopropyl trimethoxy silane" as required by claims 1, 3, 9, 12, 15, 17, 23, 29-31 and 41, produces a coating that facilitates drug delivery having adherence to a flexible silicone medical device. The instant claimed invention provides continuing adherence over deforming surfaces within medical devices. Applicants' invention is further directed to a method of making the inventive coating that allows effective drug delivery from a flexible silicone medical device that accommodates a broad spectrum of medicinal agents.

C. Teachings of Fox: Fox discloses a polymeric coating agent that uses biomedical polyurethanes as a coating vehicle. Specifically, Fox discloses that the "specific application of biomedical polyurethanes as a coating agent is superior to all other known polymeric coating materials" (Fox at page 4 lines 54-56).

D. Deficiencies of Fox: Fox does not disclose the use of a RTV silicone and urethane, wherein said RTV silicone is selected from the group consisting of methyltri-methoxy silane, methyltri-acetoxy silane, tetrachlorosilane, vinyl trimethoryl silane, organosilane ester tris[3-(trimethoxysilyl)propyl] isocyanurate, bis[trimethoxysilyl)propyl] amine and gamma-ureidopropyl trimethoxy silane as claimed in amended claims 1 and 15 from which all rejected claims depend. Within Fox there is no disclosure of combining a "RTV silicone and urethane" to provide a coating for a flexible medical device in the manner as Applicants' have claimed.

As to the composition (claims 1, 3, 9, 12, 15 and 17), Fox fails to disclose a flexible coating composition combining "RTV silicone and urethane, wherein said RTV silicone is selected from the group consisting of methyltri-methoxy silane, methyltri-acetoxy silane, tetrachlorosilane, vinyl trimethoryl silane, organosilane ester tris[3-(trimethoxysilyl)propyl] isocyanurate, bis[trimethoxysilyl)propyl] amine and gamma-ureidopropyl trimethoxy silane."

As to the method of making the flexible coating composition (claims 29-31) Applicants have cancelled claim 29, as to claims 30-31 Fox fails to disclose a method a making a flexible coating that combines "RTV silicone and urethane and a solvent."

As has been clearly enunciated by the Federal Circuit: Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention,

arranged and functioning as in the claim. Lindermann Maschinenfabrik GMBH v. American Hoist and Derrick Co., 221 USPQ 481, 485 (Fed Cir. 1984). Here the requirement of showing each and every element of Applicant's claimed invention, as set forth in amended claims 1, 15, from which all other rejected claims depend, has not been met. It is respectfully submitted that this rejection has been overcome.

IV. Rejection of claims 1-3, 8-9, 12-14, 15-17, 29-32, and 44 under 35 U.S.C. §103.

The Examiner rejected claims 1-3, 8-9, 12-14, 15-17, 29-32, and 44 under 35 U.S.C. §103 (a) as being unpatentable over Fox and further in view of Remington's Pharmaceutical Sciences. Applicants have amended claims 1, 15 and 44 as noted above to further emphasize their invention.

A. Examiner's Rejection: The Examiner states that Fox discloses a method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers and antimicrobial agents. The Examiner further states that Fox also discloses a method of preparing an infection-resistant surface, characterized by preparing a coating vehicle by dispensing a matrix forming polymeric material selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers and antimicrobial agents. Suitable biomedical silicones include the silicone rubbers, specifically SILASTIC Type A Medical Adhesive, a polydimethyl siloxane. Fox discloses the selection of a particular solvent or mixture of solvents will depend upon the specific biomedical polymeric coating agent being used as well as upon the particular antimicrobial agent or combination of agents.

The Examiner acknowledges that Fox does not disclose the addition of an emulsifier; however, Remington's Pharmaceutical Science discloses emulsifying agents, which are surfactants and/or viscosity-producing agents. The Examiner reasons that it would have been obvious to one of ordinary skill in the art to modify the composition of Fox by adding an emulsifier and a pigment as taught by Remington.

B. Applicants' Claimed Invention: The instant claimed invention as amended is directed to a coating composition including a combination of "RTV silicone and urethane wherein said RTV silicone is selected from the group consisting of methyltri-methoxy silane, methyltri-acetoxy silane, tetrachlorosilane, vinyl trimethoryl silane, organosilane ester tris[3-(trimethoxysilyl)propyl] isocyanurate, bis[trimethoxysilyl)propyl] amine and gamma-ureidopropyl trimethoxy silane." Applicants' amended claimed combination of RTV silicone and urethane produces a coating that facilitates drug delivery and enhances adherence to a flexible silicone medical device. Applicants' invention provides adherence over highly expanded surfaces within medical devices.

The instant claimed invention as amended is further directed to a method of making the inventive coating that allows effective drug delivery from a flexible silicone medical device that accommodates a broad spectrum of medicinal agents.

C. Teachings of Fox: Fox discloses a polymeric coating agent that uses biomedical polyurethanes as a coating vehicle. Specifically, Fox discloses that the "specific application of biomedical polyurethanes as a coating agent is superior to all other known polymeric coating materials" (Fox at page 4 lines 54-56).

D. Teachings of Remington: Remington's Pharmaceutical Science discloses emulsifying agents, which are surfactants and/or viscosity-producing agents.

E. Deficiencies of Cited References:

Unlike Applicants' amended claimed invention, neither cited reference, contains a flexible coating containing a mixture of "RTV silicone and urethane wherein said RTV silicone is selected from the group consisting of methyltri-methoxy silane, methyltri-acetoxy silane, tetrachlorosilane, vinyl trimethoryl silane, organosilane ester tris[3-(trimethoxysilyl)propyl] isocyanurate, bis[trimethoxysilyl)propyl] amine and gamma-ureidopropyl trimethoxy silane" with the use of an emulsifier to provide a uniform distribution of an additive compound. While Fox suggests the use of biomedical silicones, it does not disclose or suggest the use of a RTV silicone. In particular, Fox actually teaches away from Applicants' claimed invention. Fox distinguishes its invention from the prior art by stating as follows:

> "[t]he prior art, such as U.S. 4,667,143 fails to distinguish between various polymeric coating agents. The patent states that any one of a long list of resins may be mixed with an antimicrobial metal compound to provide antimicrobial coatings on medical devices. The working examples of the patent utilize either ABS polymer or alkoxy curing RTV silicone rubbers. Quite unexpectedly we have found that the specific application of biomedical polyurethanes as a coating agent is superior to all other known polymeric coating materials" (Fox at page 4 lines 51-56).

In particular, as discussed above, Fox specifically teaches away from the instant amended claimed invention by distinguishing itself from the prior art of single mixture RTV silicone by stating that "the specific application of biomedical polyurethanes as a coating agent is superior to all other known polymeric coating materials" (emphasis added). Further, Fox (like the cited '143 patent) fails to appreciate the benefits of combining RTV silicone with polyurethane.

Applicants therefore respectfully submit that the flexible coating composition as amended, in claims 1-3, 8-9, 12-14, 15-17, requires a combination of "RTV silicone and urethane wherein said RTV silicone is selected from the group consisting of methyltri-methoxy silane, methyltri-acetoxy silane, tetrachlorosilane, vinyl trimethoryl silane, organosilane ester tris[3-(trimethoxysilyl)propyl] isocyanurate, bis[trimethoxysilyl)propyl] amine and gamma-ureidopropyl trimethoxy silane." This claimed combination as amended is neither disclosed nor

suggested in either reference and therefore is not obvious under 35 U.S.C. §103(a) over Fox in view of Remington. Applicants respectfully request reconsideration of this rejection based upon Applicants' amendments.

Applicants further respectfully submit that the method of making a flexible coating composition as claimed in claims 30-32, and 44 as amended require a combination of "RTV silicone, urethane and a solvent wherein said RTV silicone is selected from the group consisting of methyltri-methoxy silane, methyltri-acetoxy silane, tetrachlorosilane, vinyl trimethoryl silane, organosilane ester tris[3-(trimethoxysilyl)propyl] isocyanurate, bis[trimethoxysilyl)propyl] amine and gamma-ureidopropyl trimethoxy silane." This method of making the flexible coating having the claimed combination as amended is neither disclosed nor suggested in either reference and therefore is not obvious under 35 U.S.C. §103(a) over Fox in view of Remington. Applicants respectfully request reconsideration and withdrawal of this rejection.

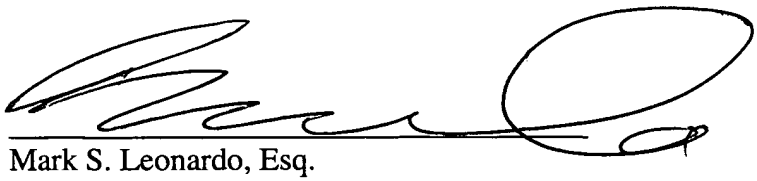
V. Allowable Subject Matter.

The Examiner indicated that claims 18-23, 26-28 and 33-41 are allowed. Applicants thank the Examiner for her diligence in the examination of these allowed claims. Examiner objected to claims 4-7 as being dependent upon a rejected base claim, but indicated that they would be allowable if rewritten in independent form including all of the limitation of the base claim and any intervening claims. Applicants have amended these objected to claims in the manner suggested by the Examiner and thank her for these suggested amendments. Applicants have additionally amended claims 30-32 to be dependant upon currently allowed claim 33, which the Examiner has indicated is allowable in its present form. Applicants have also amended claims 1, 15 and 44 to further emphasize and distinguish over the cited art.

CONCLUSION

The claims remaining within the application are believed to patentably distinguish over the prior art and to be in condition for allowance. Early and favorable consideration of this application is respectfully requested.

Respectfully submitted,



Mark S. Leonardo, Esq.
Registration No. 41,433
Customer No. 21710
Attorney for Applicant(s)

BROWN RUDNICK BERLACK ISRAELS LLP
One Financial Center, Box IP
Boston, MA 02111
(617) 856-8145
(617) 856-8201 (fax)

Dated: February 17, 2004

#1257922 v\1 - seriojc□ - ym@01!.doc□ - 20518/9